

Express Mail No. EV405281255US

<b>INFORMATION DISCLOSURE STATEMENT</b>  Address to: Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket	UCSF-085CON5
	First Named Inventor	NADEL, JAY A.
	Application Number	To Be Assigned
	Confirmation No.	To Be Assigned
	Filing Date	March 31, 2004
	Group Art Unit	To Be Assigned
	Examiner Name	To Be Assigned
	Title:	"PREVENTING AIRWAY MUCUS PRODUCTION BY ADMINISTRATION OF EGF-R ANTAGONISTS"

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. A Form PTO-SB/08A listing the references and copies of the cited references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record.

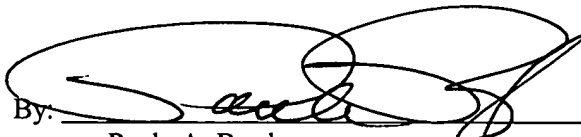
**All of the references identified herein were disclosed in parent application serial number 09/616,223 filed 7/14/2000 and as such, copies thereof are not included pursuant to the provisions of 37 CFR § 1.98(d).**

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C. § 102.

As applicants have not yet received a first Action on the merits, no fee is believed to be required for filing this Disclosure Statement. If, however, the PTO finds that for some reason a fee is due, our Deposit Account No. 50-0815, Order No. UCSF-085CON5 may be charged thereon.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: March 31, 2004

By:   
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<b>INFORMATION DISCLOSURE CITATION</b> Form PTO-1449 (Modified) <i>(Use several sheets if necessary)</i>	<b>ATTY. DOCKET NO.</b> UCSF-085 CIP	<b>SERIAL NO.</b> 09/616,223
	<b>APPLICANT</b> Nadel et al.	
	<b>FILING DATE</b> July 14, 2000	<b>GROUP</b> Unassigned

### U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
AN	5,525,625	06/11/96	Bridges et al.			
AO	6,037,361	03/14/00	Roth et al.			

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	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
AP	WO 97/19065	05/29/97	PCT				
AQ	WO 97/45412	12/04/97	PCT				
AR	WO 98/37881	09/03/98	PCT				
AS	WO 99/01421	01/14/99	PCT				
AT	WO 99/01426	01/14/99	PCT				
AU	WO 99/32121	07/01/99	PCT				
AV	WO 00/06560	02/10/00	PCT				
AW	WO 00/06561	02/10/00	PCT				
AX	WO 00/09485	02/24/00	PCT				
AY	WO 00/17162	03/30/00	PCT				

### OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AA	Donato et al (1989), "Tumor Necrosis Factor Modulates Epidermal Growth Factor Receptor Phosphorylation and Kinase Activity in Human Tumor Cells", <i>The Journal of Biological Chemistry</i> , Vol. 264(34): 20474-20481.
AB	Desseyn et al. (1997), "Human Mucin Gene MUC5B, the 10.7-kb Large Central Exon Encodes Various Alternate Subdomains Resulting in a Super-repeat", <i>The Journal of Biological Chemistry</i> , Vol. 272(6): 3168-3178.

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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		<b>APPLICANT</b> Nadel et al.	
		<b>FILING DATE</b> July 14, 2000	<b>GROUP</b> Unassigned
AC	Goldstein et al. (1995), "Biological Efficacy of a Chimeric Antibody to the Epidermal Growth Factor Receptor in a Human Tumor Xenograft Model", <i>Clinical Cancer Research</i> , Vol. 1: 1311-1318.		
AD	Kawamoto et al. (1983), "Growth stimulation of A431 cells by epidermal growth factor: Identification of high-affinity receptors for epidermal growth factor by an anti-receptor monoclonal antibody", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 80: 1337-1341.		
AE	Kondapaka et al. (1996), "Tyrosine kinase inhibitor as a novel signal transduction and antiproliferative agent: prostate cancer", <i>Molecular and Cellular Endocrinology</i> , Vol. 117: 53-58.		
AF	Levitski (1994), "Signal-transduction therapy, a novel approach to disease management", <i>Eur. J. Biochem.</i> , Vol. 226(1):1-13.		
AG	Lorimer, et al. (1995), "Immunotoxins that Target an Oncogenic Mutant Epidermal Growth Factor Receptor Expressed in Human Tumors", <i>Clinical Cancer Research</i> , Vol. 1: 859-864.		
AH	Petit et al. (1997), "Neutralizing Antibodies against Epidermal Growth Factor and ErbB-2/neu Receptor Tyrosine Kinases Down-Regulate Vascular Endothelial Growth Factor Production by Tumor Cells <i>in Vitro</i> and <i>in Vivo</i> ", <i>American Journal of Pathology</i> , Vol. 151(6): 1523-1530.		
AI	Powis (1994), "Signaling pathways as targets for anticancer drug development", <i>Pharmac. Ther.</i> , Vol. 62:57-95.		
AJ	Schmidt et al. (1996), "Targeted inhibition of tumour cell growth by a bispecific single-chain toxin containing an antibody domain and TGF $\alpha$ ", <i>British Journal of Cancer</i> , Vol. 74: 853-862		
AK	Takeyama et al. (1998), "Neutrophil-dependent goblet cell degranulation: role of membrane-bound elastase and adhesion molecules", <i>Am. J. Physiol.</i> , Vol. 275:294-302.		
AL	Temann et al. (1997), "A Novel Role for Murine IL-4 <i>In Vivo</i> : Induction of MUC5AC Gene Expression and Mucin Hypersecretion", <i>Am J. Respir. Cell Biol.</i> , Vol. 16:471-478.		
AM	Ullrich et al. (1984), "Human epidermal growth factor receptor cDNA sequence and aberrant expression of the amplified gene in A431 epidermoid carcinoma cells." <i>Nature</i> , Vol. 309(5967):418-25.		
AZ	Brown (1999), "Clinical Studies with matrix metalloproteinase inhibitors." <i>APMIS</i> , Vol. 107:174-180.		
BA	Grandis, jr., et al. (1997), "Inhibition of epidermal growth factor receptor gene expression and function decreases proliferation of head and neck squamous carcinoma but not normal mucosal epithelial cells." <i>Oncogene</i> , Vol. 15(4):409-416.		
BB	Kumar et al. (1998), "Cooperative interaction of autocrine and paracrine mitogens for airway epithelial cells." <i>Cell Biology and Toxicology</i> , Vol. 14(4):293-299.		
BC	Lee et al. (2000), "Leukotriene Receptor Antagonists and Synthesis Inhibitors Reverse Survival in Eosinophils of Asthmatic Individuals." <i>American Journal of Respiratory and Critical Care Medicine</i> , Vol. 161(6):1881-1886.		
BD	Prenzel et al. (1999), "EGF receptor transactivation by G-protein-coupled receptors requires metalloproteinase cleavage of proHB-EGF." <i>Nature</i> , Vol. 402:884-888.		
BE	Takeyama et al. (1999), "Epidermal growth factor system regulates mucin production in airways." <i>Proceedings of the national Academy of Sciences USA</i> , Vol. 96(6):3081-3086.		
BF	Takeyama et al. (2000), "Oxidative stress causes mucin synthesis via transactivation of epidermal growth factor receptor: role of neutrophils." <i>Journal of Immunology</i> , Vol. 164(3):1546-1552.		
BG	Wojtowicz-Praga et al. (1997), "Matrix metalloproteinase inhibitors." <i>Investigational New Drugs</i> . Vol. 15:61-75.		

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<b>SUPPLEMENTAL INFORMATION DISCLOSURE CITATION</b> Form PTO-1449 (Modified) <i>(Use several sheets if necessary)</i>	ATTY. DOCKET NO. UCSF-085CIP	SERIAL NO. 09/616,223
	APPLICANT Nadel, et al.	
	FILING DATE July 14, 2000	GROUP Unassigned

### U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

### FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No

### OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AA	Grandis et al. (July 24, 1997), "Inhibition of Epidermal Growth Factor Receptor Gene Expression and Function Decreases Proliferation of Head and Neck Squamous Carcinoma but not Normal Mucosal Epithelial Cells." <i>Oncogene</i> , Vol. 15(4):406-416
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PTO/SB/08A (08-00)

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	09/616,223	
			Filing Date	July 14, 2000	
			First Named Inventor	Nadel, et al.	
			Group Art Unit	1614	
			Examiner Name	Zara, Jane	
Sheet	1	of	1	Attorney Docket Number	UCSF-085CIP

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	U.S. Patent Documents		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, columns, lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS								
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Foreign Patent Documents			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	<small>Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.</small>	T <sup>2</sup>
		GUZMAN, et al. "Epidermal growth factor regulates expression of the mucous phenotype of rat tracheal epithelial cells", <i>Biochem. Biophys. Res. Com.</i> , (1995) Vol. 217(2): 412-418.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	09/616,223	
			Filing Date	July 14, 2000	
			First Named Inventor	NADEL, JAY A.	
			Art Unit	1635	
Sheet	1	of	1	Examiner Name	ZARA, JANE
				Attorney Docket Number	UCSF-085CIP

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)				
		US- 5,559,111 (HU P9501230A)		09-24-1996	Guschke	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	<b>APPLICANT</b> Nadel et al.	
	<b>FILING DATE</b> July 14, 2000	<b>GROUP</b> 1614

### U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

### FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation
AA WO 00/10588 A3	03/02/2000	PCT			<div style="display: flex; justify-content: space-between;"> <span>Yes</span> <span>No</span> </div>

### OTHER ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*


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<b>Notice of References Cited</b>	Application/Control No. 09/616,223	Applicant(s)/Patent Under Reexamination NADEL ET AL.	
	Examiner Jane Zara	Art Unit 1635	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-,306,874 B1	10-2001	Fraley et al.	514/300
	B	US-			
	C	US-			
	D	US-			
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**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Giorgio Palu' et al., In pursuit of new developments for gene therapy of human diseases, JOURNAL OF BIOTECHNOLOGY, 68 (1991) pp. 1-13
	V	Stanley T. Crooke, Antisense Research and Application, pp. 1-50
	W	Andrea D. Branch, A good antisense molecule is hard to find, TIBS 23 - February 1998, pp. 45-50
	X	Karen Pihl-Carey, Isis To Crohn's Disease Drug Fails In Phase III, BIOWORLD TODAY, Vol. 10, No. 239, pp. 1-2

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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	Examiner Jane Zara		Art Unit 1635	Page 1 of 1

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	A	US-,306,874 B1	10-2001	Fraley et al.	514/300
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**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Giorgio Palu' et al., In pursuit of new developments for gene therapy of human diseases, JOURNAL OF BIOTECHNOLOGY, 68 (1991) pp. 1-13
	V	Stanley T. Crooke, Antisense Research and Application, pp. 1-50
	W	Andrea D. Branch, A good antisense molecule is hard to find, TIBS 23 - February 1998, pp. 45-50
	X	Karen Pihl-Carey, Isis To Crohn's Disease Drug Fails In Phase III, BIOWORLD TODAY, Vol. 10, No. 239, pp. 1-2

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	Examiner <b>Jane Zara</b>		Art Unit <b>1635</b>	Page 1 of 1

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U	Masui et al. Cancer Res. 1984 Vol. 44, pp. 1002-1007.
V	Yoneda et al. Cancer Res. 1991. Vol. 51, pp. 4430-4435.
W	Khetarpal et al. Drug Metabolism and Disposition. 1994. Vol. 22, No. 2, pp. 216-223.
X	Buchdunger et al. Proc. Natl. Acad. Sci. USA 1994 Vol. 91, pp. 2334-2338.

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